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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,718	09/28/2000	Vadim N. Gladyshev	4239-56113	1779

7590

12/03/2002

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/03/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/676,718

Applicant(s)

GLADYSHEV ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-53, 55, 60, 63, 64 and 66-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 51-53, 55, 60, 63, 64 and 66-82 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☒ Other: *election facsimile cover sheet*.

### **DETAILED ACTION**

1. The election with traverse filed September 3, 2002 in Paper No. 10 is acknowledged and has been entered.
2. The amendment filed September 3, 2002 as part of Paper No. 10 is acknowledged and has been entered. Claims 1-26, 29-34, 36-50, 54, 56-59, 61, 62, and 65 have been canceled. Claims 51-53, 55, 60, 63, and 64 have been amended. Claims 66-82 have been added.
3. Claims 51-53, 55, 60, 63, 64, and 66-82 are pending in the application and are currently subject to restriction and additional election requirement.

### ***Election/Restrictions***

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 51-53, 55, 60, 63, 64, 66-77, and 80-82, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises contacting a sample with a specific binding agent that specifically binds a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 7.23.

Group II. Claims 51-53, 55, 60, 63, 64, 66-77, and 80-82, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises contacting a sample with a specific binding agent that specifically binds a mammalian 15 kDa selenoprotein having an amino acid sequence that is

at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 7.23.

Group III. Claims 51-53, 55, 60, 63, 64, 66-69, 78, and 79, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises determining the expression of a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1 by administering <sup>75</sup>Se to the subject, classified in class 424, subclass 1.11.

Group IV. Claims 51-53, 55, 60, 63, 64, 66-69, 78, and 79, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises determining the expression of a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4 by administering <sup>75</sup>Se to the subject, classified in class 424, subclass 1.11.

Group V. Claims 51-53, 55, 60, 63, 64, 66-69, and 80-82, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises Northern blotting of an mRNA coding for a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 6.

Group VI. Claims 51-53, 55, 60, 63, 64, 66-69, and 80-82, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises Northern blotting of an mRNA coding for a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 6.

Group VII. Claims 51-53, 55, 60, 63, 64, 66-69, and 80-82, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises Southern blotting of a DNA encoding a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 6.

Group VIII. Claims 51-53, 55, 60, 63, 64, 66-69, and 80-82, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises Southern blotting of a DNA encoding a mammalian 15 kDa selenoprotein having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 6.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups I-VIII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

6. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642

slr

November 19, 2002

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ART UNIT 1642



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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